UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

SECURITIES AND EXCHANGE COMMISSION, Plaintiff, v. CASSAVA SCIENCES, INC.; REMI BARBIER; and LINDSAY BURNS, Defendants.	Case No. 24-cv-1150 JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Securities and Exchange Commission ("SEC" or "Commission") alleges as follows:

SUMMARY

1. This case involves Defendant Cassava Sciences, Inc.'s ("Cassava") misleading statements about the results of its Phase 2b clinical trials for Cassava's drug candidate PTI-125,[1] a potential therapy for the treatment of Alzheimer's disease, and the role of Defendants Remi Barbier, Cassava's founder and former Chairman and CEO, and Dr. Lindsay Burns, Cassava's former Senior Vice President

[1] PTI-125 is also known as simufilam.

of Neuroscience, in those disclosures. The announced final Phase 2b results were misleading in five ways.

2. First, Cassava claimed that "[b]ioanalyses were conducted under blinded conditions to eliminate any possibility of bias." That statement negligently omitted material information. Dr. Hoau-Yan Wang, a professor at City University of New York ("CUNY"), ran clinical laboratory tests on Cassava's behalf for Phase 2b. Before Dr. Wang began running the bioanalyses, Dr. Burns negligently provided information sufficient to allow Dr. Wang to partially unblind himself.

3. Second, Defendants negligently did not disclose that the announced results of the bioanalyses were performed by Dr. Wang, the co-inventor of PTI-125, Cassava consultant, and member of Cassava's Scientific Advisory Board. Instead, public filings with the SEC referred to Dr. Wang's laboratory at CUNY generally as an "academic lab," which although technically correct, was incomplete and misleading. By Cassava failing to name Dr. Wang, investors were not made aware that the scientist performing the analysis had a conflict of interest due to his professional and financial ties to Cassava.

4. Third, Cassava conducted an audit of Dr. Wang's laboratory at CUNY in 2022, and Cassava and Barbier negligently did not disclose the audit report's finding that Dr. Wang's laboratory was "**unacceptable** and **temporarily not qualified** to provide biomarker analysis and research for services for any future Cassava studies." (Emphases in original).

5. Fourth, Cassava and Dr. Burns negligently failed to fully disclose Dr. Burns's removal of a large portion of patients in reported cognition data. The reported episodic memory results excluded data from 40% of patients who completed the cognition test. Cassava and Dr. Burns failed to disclose the average change in errors from baseline to day 28 for the full episodic memory data set (i.e., -3.4 points for the placebo group, -2.8 points for the 50 mg group, and -0.0 points for the 100mg group), which showed no similar directional improvement for either the 50 mg or 100 mg group compared with placebo. And Cassava and Dr. Burns did not disclose that Dr. Burns was unblinded when she decided which patients to exclude from the reported results.

6. Fifth, Cassava and Dr. Burns negligently failed to disclose that the spatial working memory measurement reported in the Phase 2b results as showing cognitive improvement of up to 46% was a measurement selected by Dr. Burns only after she was unblinded. Cassava and Dr. Burns also failed to disclose that other spatial working memory results, including measurements identified as "key" prior to unblinding, did not show directional improvement in patients receiving PTI-125 compared with placebo.

7. In September 2020, Cassava announced final Phase 2b results that claimed that PTI-125 taken for 28 days significantly improved every measured biomarker for Alzheimer's disease compared with subjects who took a placebo. Cassava also announced that patients who took PTI-125 showed improved cognition compared to patients who took the placebo.

8. Remi Barbier, Cassava's founder and former Chairman and CEO, participated in making Cassava's misleading statements about Phase 2b. In addition to providing information sufficient to partially unblind Dr. Wang, Dr. Burns was responsible for compiling misleading Phase 2b cognition results.

9. After Cassava reported its Phase 2b trial results, the company raised more than $260M in new funding.

JURISDICTION AND VENUE

10. The SEC brings this action pursuant to the authority established in Sections 20(b) and 20(d) of the Securities Act of 1933 ("Securities Act") [15 U.S.C. § 77t(b) and (d)].

11. This Court has jurisdiction over this action pursuant to Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)].

12. Venue is proper in this district pursuant to Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)], because Cassava is headquartered within this District, and Dr. Burns and Barbier reside within this District.

13. Defendants, directly or indirectly, have made use of the means or instruments of transportation or communication in interstate commerce or of the mails in connection with the transactions, acts, practices, and courses of business alleged herein.

DEFENDANTS

14. **Cassava Sciences, Inc. ("Cassava")** is a Delaware corporation with its principal place of business in Austin, Texas. Cassava is a pharmaceutical company

with one primary drug candidate, PTI-125, a potential therapeutic for the treatment of Alzheimer's disease. Cassava's shares are registered with the Commission pursuant to Securities and Exchange Act of 1934 ("Exchange Act") Section 12(b) and are listed on the Nasdaq Capital Market under the symbol "SAVA."

15. **Remi Barbier**, age 64, is the Founder, and was Chair, and Chief Executive Officer of Cassava until July 2024. He is a resident of Austin, Texas.

16. **Dr. Lindsay Burns**, age 59, was the Senior Vice President of Neuroscience at Cassava until July 2024. She is a resident of Austin, Texas. Dr. Burns co-invented PTI-125 with Dr. Wang.

OTHER RELEVANT PARTY

17. **Dr. Hoau-Yan Wang**, age 67, is a tenured associate professor at the City University of New York's School of Medicine. Dr. Wang co-invented PTI-125 along with Dr. Burns. Dr. Wang served on Cassava's Scientific Advisory Board, and Cassava retained Dr. Wang as a paid consultant until the company terminated his consulting agreement in June 2024.

FACTS

A. Cassava's Background

18. Barbier founded the company now known as Cassava in 1998. The relationship between the company now known as Cassava and Dr. Wang dates back to the early 2000s. Dr. Wang served as a consultant to the company until June 2024.

19. Dr. Burns was Dr. Wang's main point of contact at Cassava. Dr. Burns and Dr. Wang collaborated as co-authors on multiple scientific journal articles and

grant applications throughout the time that Dr. Wang served as a consultant to the company.

20. Dr. Wang and Dr. Burns discovered the molecule PTI-125, later named simufilam, which they claim binds to altered Filamin A proteins and remediates Alzheimer's disease-related pathology.

B. Cassava's Initial PTI-125 Trials

21. Clinical trials for a new drug usually proceed through three phases before the FDA will consider a New Drug Application.

22. In 2017, the FDA cleared Cassava's Investigational New Drug application for PTI-125, which allowed Cassava to begin clinical trials of the drug in humans. That same year, Cassava completed a Phase 1 human safety trial of PTI-125.

23. In 2019, Cassava ran what it called a Phase 2a trial, consisting of 13 Alzheimer's patients who all took doses of PTI-125 for 28 days. There was no placebo group.

24. One key objective of Cassava's Phase 2a trial was to measure changes in concentration of biomarkers—substances in cerebrospinal fluid ("CSF") believed to correspond with Alzheimer's disease pathology, neuroinflammation, and neurodegeneration. To measure changes in biomarkers, CSF was collected from patients before taking the drug and again after 28 days of treatment.

25. Cassava asked Dr. Wang to analyze the CSF samples collected from the Phase 2a participants. According to Dr. Wang's results, all 13 patients showed

directional improvements in multiple biomarkers, suggesting that the drug may be causing changes in biomarker levels.

26. In public announcements and SEC filings, Cassava disclosed that Dr. Wang and his laboratory at CUNY performed the biomarker tests for Phase 2a.

C. Cassava's Phase 2b Trial

27. In 2019, Cassava designed and began its Phase 2b clinical trial. That trial ultimately included 64 patients separated into three groups—one placebo group, one group taking a 50mg dose, and another group taking a 100mg dose. Each patient in each group was to take their respective treatment for 28 days.

28. Phase 2b was to be conducted as a double-blinded clinical trial, which means neither the patient nor the tester is aware which patient received which treatment. Blinding is a standard practice in many clinical trials, in part because it helps reduce the potential impact of bias.

29. Participants in Phase 2b had CSF drawn before treatment began and again after 28 days of treatment. Pursuant to the testing protocol, Cassava directed each clinical site to send patient CSF samples to the CUNY laboratory in New York where Dr. Wang performed research to be stored before laboratory analysis. Laboratory results were to be sent directly to Dr. Burns who then was to forward them to a biostatistics company hired by Cassava to compile unblinded results.

30. Participants in Phase 2b also took a battery of cognition tests before treatment and then again after 28 days to assess any changes in cognition. Those

results were also sent first to Dr. Burns who then forwarded them to the biostatistics company to perform statistical analyses on unblinded test results.

1) Round 1 Biomarker Testing

31. Cassava initially hired a laboratory in Europe to test the Phase 2b CSF samples for nine biomarkers. However, there were two biomarkers that Cassava wanted tested that the European laboratory could not measure. Cassava asked Dr. Wang to test CSF samples for those two biomarkers. All biomarker testing by the European lab (seven tests) and Dr. Wang (two tests) (collectively, "Round 1") were completed by early May 2020. Results were sent to Dr. Burns who forwarded them to the biostatistics company.

32. On May 15, 2020, Cassava filed a Form 8-K with the Commission, attaching a press release with the headline "Top-line Results from a Phase 2b Study of PTI-125 in Alzheimer's Disease Does Not Meet Primary Endpoint."

33. None of the tests performed by the European lab showed a meaningful effect of the drug treatment arms compared with the placebo. The Phase 2b Round 1 results also did not show a drug effect consistent with Dr. Wang's Phase 2a results.

34. Dr. Burns and other Cassava employees and outside scientists expressed concern with the European laboratory's results due to unexplained data variability.

35. In its May 15, 2020, press release, Cassava declared that the "study showed high variability in levels of CSF biomarkers over 28 days" and noted that it planned to re-analyze the biomarkers with the remaining patient CSF samples.

36. After this disclosure, Cassava's stock price dropped from $7.61 a share to $1.63 a share by the end of trading that day.

2) Dr. Burns Provides Data Sufficient to Allow Dr. Wang to Partially Unblind Himself

37. On May 13, 2020, the biostatistics company sent to Dr. Burns a document summarizing the statistics for each Round 1 biomarker. The document included, among other things, statistics for the lowest (min) and highest (max) sample levels in each treatment arm and in the placebo group for Day 0 (before the trial) and Day 28 (after the trial). The document also identified the largest and smallest "change from baseline" or change in biomarker levels in each treatment arm and placebo group.

38. That same day, at Cassava's request, the biostatistics company sent Cassava the unblinding codes, which allowed Cassava to know which patients participated in each treatment group. Dr. Burns received the unblinding codes.

39. On May 14, 2020, Dr. Burns sent this document with min, max, and change from baseline data to Dr. Wang and asked him to evaluate the European laboratory's data. At the time she sent the document to Dr. Wang, Dr. Burns understood that Dr. Wang had completed the testing for two biomarkers in Round 1. She also knew that Dr. Wang had individual test results identified by patient identification code for the two biomarkers that he had tested for Round 1.

40. The document sent by Dr. Burns on May 14, 2020, had sufficient information to allow Dr. Wang to match some of the test results that he ran in Round 1 with specific reported statistics.

41. Ultimately, using the information he was provided, Dr. Wang was able to unblind himself to roughly a third of the patients in Phase 2b—eight patients in the placebo group; seven in the 50 mg group; and eight in the 100 mg group.

3) Round 2 Biomarker Testing

42. On or around June 1, 2020, Cassava directed Dr. Wang to perform a reanalysis of the Phase 2b clinical samples for the seven biomarkers tested by the European lab during Round 1 using the CSF samples remaining in his lab. Dr. Wang did not, as part of Round 2, re-run tests for the two biomarkers he analyzed in Round 1. Dr. Wang also agreed to run additional biomarker tests that had not been completed in Round 1. These combined tests constituted the Round 2 testing.

43. When Dr. Wang conducted Round 2 testing, he was partially unblinded and knew for at least some patients whether they were in the placebo group or one of the treatment arms.

44. On September 14, 2020, Cassava publicized Dr. Wang's results which showed statistically significant improvement in all biomarkers in the treatment groups as compared with the placebo group. The company issued a press release and provided an investor presentation with an accompanying slide deck, all of which were filed with the Commission under Form 8-K.

45. The September 14, 2020, press release stated, "Bioanalyses were conducted under blinded conditions to eliminate any possibility of bias. An academic lab generated final results."

4) Phase 2b Cognitive Testing

46. The Phase 2b trial included cognition testing in addition to biomarker analysis. Patients in the Phase 2b trial took the Cambridge Neuropsychological Test Automated Battery ("CANTAB"), a group of cognitive testing. The CANTAB administered in Phase 2b included four different types of tests, each measuring different neurological functions. Patients were tested prior to receiving the drug (or placebo) and again after 28 days.

47. The primary CANTAB test for Alzheimer's patients was the Paired Associates Learning Total Errors Adjusted ("PALTEA"), which measures episodic memory. Cassava's two mandatory reports, its Statistical Analysis Plan ("SAP") and Trial Protocol, said that it would report statistics for *all subjects tested* as part of its cognitive testing.

48. Dr. Burns received the PALTEA results in May 2020. The data showed no improvement in episodic memory in the drug treatment arms compared with the placebo group and they showed no meaningful improvement in patient cognition.

49. After receiving these results, Dr. Burns, who was unblinded, first removed patients with missing data and patients who did not take the drug and then engaged in what she described as a "sensitivity analysis" where she removed the highest performing patients and lowest performing patients by baseline score cutoffs

across all groups until the results appeared to show separation between the placebo group and the treatment arms.

50. Dr. Burns ultimately removed 40% of the patient population from the PALTEA analysis. The methodology or criteria of subject removal that Dr. Burns utilized is not predefined in the clinical trial protocol nor the SAP.

51. Cassava did not disclose the full results of the PALTEA, but instead reported the results of Dr. Burns' sensitivity analysis as the final results. In some disclosures, Cassava included language noting that it calculated effect sizes "after removing the most and least impaired subjects." But until a Form 8-K filed on July 1, 2024, Cassava did not inform investors in any SEC filing that the reported PALTEA excluded results from 40% of patients.

52. Phase 2b cognitive testing also included an analysis of participants' Spatial Working Memory ("SWM") as a secondary outcome. Dr. Burns relied on the test's developer to identify Key Outcome Measures, which for Spatial Working Memory were "SWM Strategy" and "SWM between errors." Neither the test creator nor Dr. Burns identified any other key SWM measurement prior to receiving unblinded results, although the total errors measure reported by Cassava is a secondary outcome measure by the test developer.

53. When the biostatistics firm provided results for the two key Spatial Working Memory measurements identified by Cassava and the test developer, neither showed a clear benefit in the treatment arms.

54. Cassava did not report results for SWM between errors or SWM strategy to investors.

55. Instead, Dr. Burns selected, and Cassava reported, another measurement after she received unblinded results—SWM total errors. This was the only SWM result that was disclosed to investors.

D. Cassava Discloses Results from Phase 2b

56. On September 14, 2020, Cassava announced the results from Phase 2b in a press release, an updated presentation, an 8-K filing with the SEC, and an investor call.

57. In its September 14, 2020, press release, Cassava announced that "Alzheimer's patients treated with 50 mg or 100 mg of [PTI-125] twice-daily for 28 days showed statistically significant ($p<0.05$) improvements in biomarkers of disease pathology, neurodegeneration and neuroinflammation, versus Alzheimer's patients who took placebo." Cassava claimed that "[b]ioanalyses were conducted under blinded conditions to eliminate any possibility of bias" and, without identifying Dr. Wang, said that an "academic lab generated final results."

58. Cassava also claimed that "Alzheimer's patients treated with [PTI-125] showed directional improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo (Effect Sizes 46-17%)."

59. Cassava also released a presentation on September 14, 2020, titled "Final Results of a Phase 2b Study of Sumifilam in Alzheimer's Disease."

60. That presentation claimed that the biomarker results from Round 1 was "invalid data," in part because some biomarkers in the placebo group "moved in opposite directions," suggesting simultaneous improving and worsening in the same patients, and that changes in biomarkers in placebo patients were uncorrelated. The presentation claimed that changes in biomarkers from Round 2 were correlated, and therefore valid.

61. The presentation claimed that the Phase 2b was a randomized, double-blind, placebo-controlled, multicenter clinical study. Cassava also claimed that PTI-125 "appears to stabilize or improve memory," noting "37% and 23% effect sizes in episodic memory vs placebo" and "17% and 46% effect sizes in spatial working memory vs placebo."

62. While the presentation did note that "*effect sizes* vs. placebo were calculated by Hedge's g after removing the most and least impaired subjects across all groups by baseline score" (emphasis added), the presentation did not disclose that the episodic memory results were from a sensitivity analysis and not from the full population.

63. The presentation did not explain that the episodic memory results were calculated only after removing 40% of the study population. The presentation failed to disclose the average change in errors from baseline to day 28 for the full episodic memory data set (i.e., -3.4 points for the placebo group, -2.8 points for the 50 mg group, and -0.0 points for the 100 mg group), which did not show similar directional improvement for either the 50 mg or 100 mg group compared with placebo.

64. The September 14, 2020, presentation also did not disclose that the key spatial working memory measurements identified by Cassava and the test developer prior to unblinding showed no improvement.

65. Cassava also held an investor call on September 14, 2020, where both Barbier and Dr. Burns were presenters.

66. On that conference call, Barbier claimed that "an academic lab conducted a second and final bioanalysis of the Phase 2b data" and that "the academic lab showed what we consider to be valid, proper, and expected data." He claimed that "ourselves and our advisors and pretty much anyone we've shown all the data to have confirmed that the second bioanalysis is a valid analysis."

67. Dr. Burns presented biomarker results and the cognitive results on the September 14, 2020 conference call. In her presentation, Dr. Burns described episodic memory results as "on average the placebo patients improved by one and half errors . . . but in contrast, the 50 mg dose group improved 5.7 errors on average resulting in a 37 percent effect size compared to that change in placebo." She continued that "the patients who took 100 milligrams improved by four and a half errors which is a 23 percent effect size."

68. Dr. Burns did not disclose during the investor call that the presented results for episodic memory were based on a sensitivity analysis. Dr. Burns also did not disclose during the presentation that the "averages" she referred to were calculated only after removing 40% of the study population. She did not disclose the average change in errors from baseline to day 28 for the full episodic memory data

set (i.e., -3.4 points for the placebo group, -2.8 points for the 50 mg group, and -0.0 points for the 100 mg group), which did not show similar directional improvement for either the 50 mg or 100 mg group compared with placebo.

69. Dr. Burns also presented the spatial working memory results, but again did not disclose that the spatial working memory test measures identified before being unblinded did not show improvements in the treatment arms compared with placebo.

70. Dr. Burns concluded by explaining that "any one of these [cognition] tests would indicate it's moving in the direction, but because we have directional improvement in both dose groups on two different tests, it gives us a lot more confidence." She explained that having both tests show directional improvement was encouraging because "it's not just two plus two, it's more like two plus two equals ten rather than four."

71. Shortly after Cassava's September 14, 2020, announcements regarding its Round 2 Phase 2b results, the company's stock more than doubled, from $3.40 to $8.41 on September 14, 2020.

72. On November 4, 2020, Cassava filed an 8-K attaching a presentation which provided additional biomarker results from Phase 2b supposedly showing that PTI-125 improved the integrity of the blood-brain barrier. Those tests were also conducted by Dr. Wang, although Cassava did not disclose that at the time. The press release and presentation continued to claim that the testing was conducted under

blinded conditions and compiled results from all Round 2 biomarker tests conducted by Dr. Wang.

73. The presentation attached to the November 4, 2020, 8-K also included results for episodic memory, but failed to disclose that any data had been excluded from the analysis.

74. On November 9, 2020, Cassava filed its Form 10-Q Quarterly Report. That report included results from Phase 2b. The 10-Q continued to claim that Phase 2b was "double-blind" and that PTI-125 "significantly ($P<0.05$) improved an entire panel of validated biomarkers of disease in patients with Alzheimer's disease compared to a placebo group" and that "Alzheimer's patients treated with [PTI-125] showed directional improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo (Effect Sizes 46-17%)." That report did not disclose that the episodic memory results excluded data from 40% of the Phase 2b participants.

75. On February 8, 2021, the Company filed a Form 8-K attaching an updated corporate presentation. The presentation summarized the biomarker results from Dr. Wang. The presentation also included the top-line results from Phase 2b cognition without disclosing that any patient data had been removed from episodic memory analysis and without disclosing that the other key spatial working memory measurements showed no improvement compared with placebo.

76. Cassava continued to include Phase 2b results in filings with the SEC, including detailed results in annual reports filed March 1, 2022, and February 28,

2023, and summaries of Phase 2b results in an annual report filed February 28, 2024, and Forms 10-Q filed April 29, 2021, August 4, 2021, November 15, 2021, May 5, 2022, August 4, 2022, November 7, 2022, May 1, 2023, August 3, 2023, November 7, 2023, and May 10, 2024. In each of those filings, Cassava claimed that the bioanalyses were conducted under blinded conditions.

77. Cassava offered and sold securities during this period, and in October 2023, Barbier and Dr. Burns received stock options from Cassava.

E. Cassava Raises Funds from Public Investors Based on Phase 2b Results

78. On November 16, 2020, Cassava filed an updated prospectus supplement to sell more than 9 million shares at $8 per share, netting Cassava around $70 million after underwriting fees. The prospectus incorporated by reference certain documents, including Form 10-Q filed November 9, 2020, Form 8-K filed September 14, 2020, and Form 8-K filed November 4, 2020.

79. In February 2021, Cassava announced that given the results of Phase 2b and prior clinical results, it planned to proceed to Phase 3.

80. Cassava subsequently filed a new shelf registration statement in February 2021 to register sales of approximately $200 million, which it executed on, netting more than $190 million after paying underwriter fees. Cassava incorporated documents into the shelf registration and subsequent prospectus, including Form 10-Q filed November 9, 2020, Form 8-K filed September 14, 2020, and Form 8-K filed November 4, 2020.

F. Publicized Concerns About Dr. Wang

81. In August 2021, two individuals filed a citizen petition with the FDA—a mechanism designed for the public to petition the FDA regarding administrative and regulatory decisions—asking the agency to perform a review of the drug and claims made by the company. Citizen petitions are public documents and, thus, Cassava was alerted to the claims contemporaneously.

82. The citizen petition included claims, that, among other things, Dr. Wang had manipulated images of tests known as western blots to various academic journals as well as, collaboratively with Cassava, to the National Institutes of Health to support grant applications.

83. Barbier and Dr. Burns were made aware of the claims raised by the citizen petition around the time it was filed.

G. Audit of Dr. Wang's Laboratory

84. Following complaints raised in the citizen petition, the FDA performed a review of Dr. Wang's laboratory at CUNY. Following the FDA's review, Cassava initiated its own audit of Dr. Wang's laboratory related to his work on the Phase 2b trial. Between April and September 2022, Cassava's Senior Director of Clinical Quality Systems reviewed documents related to the Phase 2b trial and conducted a site visit to Dr. Wang's laboratory at CUNY.

85. Cassava's audit found critical issues with the laboratory and Dr. Wang's practices, including a "lack of procedures, proper document practices, equipment and

freezer qualification, and software access control." Most notably, Cassava found a "lack of experiment logbooks/notebooks for all study/research work being performed."

86. Based on these failings, Cassava determined that Dr. Wang's laboratory at CUNY were "considered **unacceptable** and **temporarily not qualified** to provide biomarker analysis and research services for any future Cassava studies." (Emphases in original). Cassava concluded that Dr. Wang's laboratory at CUNY "should not be contracted for any further biomarker analysis and research work" until a "follow-up audit is conducted to confirm the observations have been closed out." Both Barbier and Dr. Burns were generally aware of the findings in the report. However, Cassava did not sever its relationship with Dr. Wang at that time. Nor did Cassava inform investors of Cassava's internal findings regarding Dr. Wang. It was not until June 2024 that Cassava officially ended its contractual relationship with Dr. Wang.

OVERVIEW OF SECURITIES LAW VIOLATIONS

A. Defendants Negligently Misrepresented Material Facts

87. Sections 17(a)(2) and 17(a)(3) of the Securities Act make it unlawful for any person, in the offer or sale of a security, to "obtain money or property by means of any untrue statement of material fact" or a material omission necessary to make statements made not misleading, or to "engage in any transaction, practice, or course of business which operates or would operate as a fraud or deceit upon the purchaser."

88. Defendants incorrectly claimed that Phase 2b bioanalyses were conducted under blinded conditions. Defendants negligently stated in SEC filings, press releases, presentations, and verbally that the Phase 2b bioanalyses were conducted under blinded conditions. Those statements were untrue because Dr. Wang, who performed the bioanalyses, was at least partially unblinded after receiving information from Dr. Burns in May 2020. The misstatements were material because, as even Cassava noted, "blinded conditions . . . eliminate any possibility of bias." Blinding was even more important in this instance because Dr. Wang, the co-inventor of the drug and an individual with a financial stake in its success, was the scientist performing the bioanalyses.

89. Defendants failed to disclose that Dr. Wang conducted the bioanalyses in Round 2 and Dr. Wang's laboratory was later deemed unacceptable by Cassava's internal audit. Defendants' negligent failure to name Dr. Wang or his laboratory as the parties that ran the assays deprived the investing public of the ability to consider any conflicts of interest between Dr. Wang and Cassava. It also made it considerably more difficult for investors to question whether Dr. Wang remained blinded or whether he might have manipulated results to ensure investors perceived his invention as a success. Furthermore, Defendants negligently failed to inform investors that Cassava determined pursuant to their internal audit that Dr. Wang's laboratory was unacceptable and temporarily not qualified to provide biomarker analysis and research services for any future Cassava studies.

90. Defendants misled investors by reporting cognition results that excluded 40% of subjects. Defendants negligently failed to disclose that the episodic memory results were calculated only after removing 40% of the study population until July 2024. Defendants did not disclose the average change in errors from baseline to day 28 for the full episodic memory data set (i.e., -3.4 points for the placebo group, -2.8 points for the 50 mg group, and -0.0 points for the 100 mg group), which the full data set did not show similar directional improvement for either the 50 mg or 100 mg group compared with placebo.

91. While one presentation filed with the SEC did note that "*effect sizes* vs. placebo were calculated by Hedge's g after removing the most and least impaired subjects across all groups by baseline score" (emphasis added), the presentation failed to disclose that episodic memory results displayed in the graph were from a sensitivity analysis, not from data from the full population.

92. Cassava and Dr. Burns selected a secondary outcome measurement to report for spatial working memory and did not report results from other key spatial working memory outcome measures. Dr. Burns worked with the CANTAB developer to select key secondary measurements for spatial working memory before she was unblinded. After those measurements did not show promising results, she decided to select a new spatial working memory measurement that showed improvements in treatment arms compared with placebo. By failing to disclose the other tests that did not show directional improvement and failing to disclose that Dr. Burns only selected

the reported measurement, Defendants negligently misrepresented the full truth of the results.

93. Misstatements about Phase 2b were material. PTI-125 is Cassava's primary asset and its only realistic potential source of revenue. The company's financial status leading up to the stock sales in November 2020 and February 2021 also show the materiality of the news about Phase 2b. Several banks advised the company that Cassava would be unable to raise sufficient capital for Phase 3 testing until announcing the Phase 2b results. Following the Phase 2b result disclosures, the company's stock price rose dramatically, enabling the company to raise hundreds of millions of dollars for its Phase 3 testing.

B. Recordkeeping and Reporting Requirements

94. Section 13(a) of the Exchange Act and Rules 13a-1, 13a-11 and 13a-13 thereunder require issuers to timely file annual, current and quarterly reports, respectively, with the Commission. Implicit in these provisions is the requirement that the information provided be accurate. Exchange Act Rule 12b-20 requires that periodic reports contain all information necessary to ensure that statements made in them are not materially misleading.

95. Cassava made its misstatements in at least 15 publicly filed annual and quarterly disclosures between September 14, 2020 and February 2024 and in multiple periodic filings. Following notice of the issues related to potential biomarker test manipulation in 2021, Cassava continued to both affirmatively include misrepresentations in its publicly filed disclosures and presentations as well as

incorporate prior misrepresentations by reference into its continued disclosures. Barbier was ultimately responsible for ensuring the accuracy of the company's filings, and he filed quarterly certifications declaring that the disclosures were accurate. Dr. Burns should have known that certain provisions of the company's filings contained misleading information.

FIRST CLAIM FOR RELIEF

(Against Cassava for Violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (3)])

96. The SEC realleges and incorporates by reference paragraphs 1 through 95 above.

97. By reason of the conduct described above, Cassava, in the offer or sale of securities, by use of the means or instruments of transportation or communication in interstate commerce or by use of the mails, directly or indirectly: (i) obtained money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (ii) engaged in transactions, practices, or courses of business which operated or would operate as a fraud or deceit upon the purchaser. As alleged above, Cassava's negligent actions included: stating in public filings that the Phase 2b study was conducted under "blinded conditions;" reporting that the Phase 2b study was conducted by an "academic lab" and failing to name Dr. Wang or the subsequent findings against him by Cassava's internal audit; portraying a sensitivity analysis related to the Phase 2b

episodic cognitive results as the full and final results of the clinical trial; and failing to disclose that the spatial working memory measurement reported in the Phase 2b results was a post-hoc measurement selected by Dr. Burns in place of pre-selected measurements that did not show positive outcomes.

98. While engaging in the conduct described above, Cassava acted negligently.

99. By engaging in the conduct described above, Cassava violated, and unless restrained and enjoined will continue to violate, Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (3)].

SECOND CLAIM FOR RELIEF

(Against Barbier for Violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (3)])

100. The SEC realleges and incorporates by reference paragraphs 1 through 95 above.

101. By reason of the conduct described above, Barbier, in the offer or sale of securities, by use of the means or instruments of transportation or communication in interstate commerce or by use of the mails, directly or indirectly: (i) obtained money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (ii) engaged in transactions, practices, or courses of business which operated or would operate as a fraud or deceit upon the purchaser. As alleged above, Barbier's negligent actions

included: reporting that the Phase 2b study was conducted by an "academic lab;" failing to name Dr. Wang as the sole scientist conducting the biomarker analysis for Phase 2b; and failing to disclose that Cassava deemed Dr. Wang's laboratory unacceptable pursuant to an internal audit.

102. While engaging in the conduct described above, Barbier acted negligently.

103. By engaging in the conduct described above, Barbier violated, and unless restrained and enjoined will continue to violate, Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (3)].

THIRD CLAIM FOR RELIEF

(Against Dr. Burns for Violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (3)])

104. The SEC realleges and incorporates by reference paragraphs 1 through 95 above.

105. By reason of the conduct described above, Dr. Burns, in the offer or sale of securities, by use of the means or instruments of transportation or communication in interstate commerce or by use of the mails, directly or indirectly: (i) obtained money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (ii) engaged in transactions, practices, or courses of business which operated or would operate as a fraud or deceit upon the purchaser. As alleged above, Dr. Burns' negligent actions

included: stating in public filings that the Phase 2b study was conducted under "blinded conditions;" portraying a sensitivity analysis related to the Phase 2b episodic cognitive results as the full and final results of the clinical trial; and failing to disclose that the spatial working memory measurement reported in the Phase 2b results was a post-hoc measurement selected by Dr. Burns in place of pre-selected measurements that did not show positive outcomes.

106. While engaging in the conduct described above, Dr. Burns acted negligently.

107. By engaging in the conduct described above, Dr. Burns violated, and unless restrained and enjoined will continue to violate, Sections 17(a)(2) and 17(a)(3) of the Securities Act [15 U.S.C. §§ 77q(a)(2) and (3)].

FOURTH CLAIM FOR RELIEF

(Against Cassava for Violating Section 13(a)(1) of the Securities Act and Rules 12b-20, 13a-1, 13a-11, and 13a-13 thereunder [15 U.S.C. § 78m(a) and 17 C.F.R. § 240.12b-20, 13a-1, 13a-11, and 13a-13])

108. The SEC realleges and incorporates by reference paragraphs 1 through 95 above.

109. Cassava violated Exchange Act Section 13(a)(1) and Exchange Act Rules 12b-20, 13a-1, 13a-11, and 13a-13 thereunder by including false and misleading information in disclosure documents filed with the Commission pursuant to the Exchange Act.

110. By engaging in the conduct described above, Cassava violated, and unless restrained and enjoined will continue to violate Exchange Act Section 13(a)(1) and Exchange Act Rules 12b-20, 13a-1, 13a-11, and 13a-13 thereunder.

PRAYER FOR RELIEF

WHEREFORE, the SEC respectfully requests that the Court enter a Final Judgment:

I.

Finding that Defendants committed the alleged violations;

II.

Permanently enjoining all Defendants, their agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, who receive actual notice of the judgment by personal service or otherwise, from violating Securities Act Section 17(a) [15 U.S.C. § 77q(a)];

III.

Permanently enjoining Cassava, its agents, servants, employees, and attorneys, and those persons in active concert or participation with any of it, who receive actual notice of the judgment by personal service or otherwise, from violating Exchange Act Section 13(a)(1) [15 U.S.C. § 78m(a)] and Exchange Act Rules 12b-20, 13a-1, 13a-11, and 13a-13 [17 C.F.R. § 240.12b-20, 13a-1, 13a-11, and 13a-13];

IV.

Ordering Defendants to pay civil penalties pursuant to Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)];

V.

Pursuant to the Court's inherent authority to fashion appropriate equitable relief in this matter, prohibiting Barbier and Burns from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Exchange Act [15 U.S.C. § 78l] or that is required to file reports pursuant to Section 15(d) of the Exchange Act [15 U.S.C. § 78o(d)];

VI.

Retaining jurisdiction of this action in accordance with the principles of equity and the Federal Rules of Civil Procedure in order to implement and carry out the terms of all orders and decrees that may be entered, or to entertain any suitable application or motion for additional relief within the jurisdiction of this Court; and

VII.

Granting such other and further relief as this Court may determine to be just and necessary.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff Securities and Exchange Commission demands that this case be tried to a jury.

Dated: Washington, D.C.
September___, 2024

Respectfully submitted,

By: _____

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